Attachment to Staff Paper # 26

FRAMEWORK FOR REFINING FQPA SCIENCE POLICIES

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
① Applying the FQPA 10-Fold Safety Factor	Begin with assumption that the FQPA safety factor is to be applied. OPP interdivisional committee reviews data, makes recommendation to OPP management: • If no or very little exposure to women, infants and children, recommend removing FQPA factor • If significant exposures to infants and children, weigh evidence, determine if adequate safety is assured -- Retain if lack information on susceptibility differences -- Retain some or all where evidence shows additional sensitivity with unequivocal, significant adverse effects of concern with elements such as severity, irreversibility, dose-response characteristics or other indications that children's safety may not otherwise be assured -- Retain where fundamental information on likelihood of exposure at levels higher than exposure estimates is lacking • Where further data on toxicity or exposure needed, evaluate available data and decide based on weight of evidence whether safety factor must be retained or not	• Brief the SAP on the Agency's response to its March 1998 comments • Develop general guidance (describing scientific basis for 10X policy) and working level (procedural) guidance, based on SAP and Intra-agency working group recommendations • Issue draft guidance documents for public comment (30 days) • Hold public workshop to discuss • Issue final guidance	• July 1998 • December 1998 • January 1999 • March 1999

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
② Dietary Exposure Assessment – Whether and How to Use Monte Carlo Analyses and the 99.9 percentile issue	• Regulate at the 95th percentile where actual or proposed tolerance levels are used in the risk assessment • Regulate at the 99.9th percentile where more realistic residue information is available	• USDA to address issues of accuracy of reported high-end consumption values • Develop statistical methods for use of composite data to estimate exposure from single-serving-sized food items • Complete draft guidance on use of Monte Carlo estimates, issue for public comment	• Sept/Oct 1998 • Draft November 1998 • Final March 1999 • October 1998 • Final January 1999
③ Exposure Assessment – Interpreting "No Residues Detected."	• If tests show pesticide use does not leave residues, EPA finds “reasonable certainty of no finite residues” and treats as zero for risk assessment • If tests show pesticide use does leave residues and residues are potentially significant (even if not detectable), ½ the level of detection is used for risk assessment	• Better define “no expectation of finite residues” (i.e., when is zero actually zero) • Describe appropriate statistical methods for incorporating non-detectable residues into risk assessments • Describe use limit of detection vs. limit of quantitation • Issue final guidance covering the three topics	• October 1998 • October1998 • October 1998 • February 1999

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
④ Dietary Exposure Estimates	• Residue levels and food consumption are key to dietary exposure estimation • Initial assumption is tolerance-level residues, which is refined based on available data on actual residues and percent crop treated if unacceptable risk found at the higher level • EPA meets with registrants early in the reregistration process to obtain updated use information • EPA has acquired capability to perform exposure assessments using state-of-the-art software and current USDA food consumption data	• Provide updated matrices of use/usage data to growers, plus schedule of chemicals to be reviewed • Complete development of National Pesticide Residue Database (EPA) • Updated USDA food consumption information available to EPA • Guidance for growers, states, etc. regarding need for use information	• December 1998 • October 1998 • Mid-1999

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
⑤ Drinking Water Exposures	• Scenarios and models used as screening tools, based on registrant data on persistence, mobility plus environmental conditions (e.g., soil type, rainfall) -- Those that pass are not evaluated further -- For those that fail, EPA seeks additional data, e.g., USGS monitoring data • Final decision based on weight of all available evidence and a reasonable, protective estimate of exposure, not worst-case or artificially high estimates	• Presentation to SAP of (1) reservoir scenario as replacement for farm pond; (2) OPP's preliminary evaluation of watershed scale models, including ACPA's regression approach • Publish draft document describing reservoir modification for public review and comment • Workshops on drinking water and residential exposure assessment • Issue final description of new models • ILSI workshop to develop framework for data and model development for probabilistic aggregate exposure assessment • Issue HED standard operating procedure for comment after revisions	• July 1998 • November 1998 • September 1998 • January 1999 • February 1999 • December 1998 • Draft March 1999 • Final June 1999

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
⑥ Assessing Residential Exposure	• EPA uses Standard Operating Procedures, which include 14 use sites and 42 use scenarios within those sites to model residential and other non-dietary, non-occupational exposures	• Complete revision of SOPs to incorporate SAP comments; release for public comment • Complete final revised SOPs • Receive Phase 1 report of Indoor Residential Exposure Joint Venture Task Force • Receive Phase 2 report; review results and use as appropriate • Receive results of Outdoor Residential Exposure Task Force; review results and use as appropriate	• December 1998 • March 1999 • March 1999 • October 2000 • August 1999
⑦ Aggregating Exposures from all Non-Occupational Sources	• EPA adds risks across sources of exposure for which there is reliable quantitative information • If quantitative information is not available, EPA uses upper bound modeling data to determine if risk from the source is likely to contribute only minimally to aggregate risk (and therefore is acceptable)	• Develop aggregate exposure assessment guidance; release for public comment • Develop internal working guidance; release for public comment • Publish final guidances	• March 1999 • March 1999 • June 1999

SCIENCE POLICY AREA	CURRENT APPROACH	NEXT STEPS	TIMING
⑧ How to conduct a cumulative risk assessment for organophosphates or other pesticides with a common mechanism of toxicity	• Cumulative risk assessments are being deferred until adequate methods are available	• ILSI workshop • Develop draft guidance; release for public comment • Issue final guidance • Release Guidance for Id'ing Pesticides with Common Mechanism • Publish final guidance	• September 1998 • May 1999 • August 1999 • August 1998 • November 1998
⑨ Selection of Appropriate Toxicity Endpoints (or critical effects) for Risk Assessments of Organophosphates	• EPA uses either plasma, red blood cell, or brain cholinesterase inhibition as the basis for determining critical effect levels and setting reference doses.	• Publish current draft guidance for public comment (based on 1997 SAP presentation) • Issue final guidance	• October 1998 • December 1998